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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/698,789 | 10/27/2000 | Michael Spencer | DEKM:157USC1 | 7335 |

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| EXAMINER | |
| KRUSE, DAVID H | |
| ART UNIT | PAPER NUMBER |
| 1638 | |

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,789

Applicant(s)

SPENCER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-87 and 96-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-87 and 96-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Arguments filed 4 February 2003.
2. The Specification is now in compliance with the Sequence Rules in view of the amendment filed 4 February 2003.
3. Applicant has perfected the claim of priority under 35 USC § 120.
4. The PCT Search Report for PCT/US98/06640 has been considered and the appropriate line on the IDS Form 1449, filed 26 March 2001 has been initialed, a copy is attached hereto. Applicant should be advised that PCT search reports are not considered proper references to be published on the face of the Patent.
5. Formal drawings were filed 4 February 2003. The draftsman has objected to Figure 13, see attached PTO-948. The Examiner recommends that Figure 13 be reconfigured to keep all of the rows for each column on one page to avoid confusion. In addition, the individual pages of Figure 13 should be labeled 13A, 13B etc. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.
6. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

8. Claims 83-87 and 96-99 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 October 2002. Applicant's arguments filed 4 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the claims are directed to a method of plant breeding and not to corn plants that are capable of being rendered male-sterile by treatment with glyphosate. Applicant argues that the relevant inquiry is not whether written description has been established with respect to plants exhibiting glyphosate-inducible male sterility *per se*, but rather whether the claimed method has been adequately described to show possession of the invention (page 5, 1st paragraph of the response). This argument is not found to be persuasive because Applicant has not adequately described the genus of maize plants comprising a first EPSPS transgene that is capable of being rendered male-sterile by treatment of said plant with glyphosate that is required to practice the claimed method.

Applicant argues the 'GG25' and 'GJ11' are transformation events and not maize lines and that these events may be transferred by plant breeding techniques into essentially any other maize plant (page 5, 2nd paragraph of the response). This argument is not found to be persuasive because the instant claims are not limited to

maize plants comprising a first EPSPS transgene that is capable of being rendered male-sterile by treatment of said plant with glyphosate that are produced from 'GG25' or 'GJ11'.

Applicant argues that the working Examples provide further description of the invention (page 5, 3rd paragraph, and page 6, 1st paragraph of the response). This argument is not found persuasive for the reason give supra.

Applicant argues that the data in the specification demonstrates the invention of glyphosate-inducible male sterility (page 6, 2nd paragraph of the response). This argument is not found to be persuasive because the conditional phenotype described in varieties 'GG25' and 'GJ11' are admitted by Applicant to be elite events, but it remains unclear from the instant specification that Applicant has adequately described a method of reproducing such elite events in other maize plants without using varieties 'GG25' and 'GJ11'.

Applicant addresses the Feng Declaration filed under 37 CFR § 1.132, on 4 February 2003 (paragraph spanning pages 6-7 of the response). The Feng Declaration addresses evidence that in histological studies in transgenic maize demonstrated that glyphosate arrested the maturation of microspore pollen cells, resulting in inviable pollen and male sterility. Additional evidence produced by the Feng Declaration indicates that other maize plants produced by transforming with a construct comprising an expression-optimized CaMV35s promoter upstream of a non-translated leader sequence from *Petunia hybrida* hsp70 (heat shock protein 70) lined to a glyphosate-tolerant EPSPS (CP4) produce transformed maize plant that could be made male sterile

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by the application of glyphosate (pages 5-6 of the Feng Declaration). The Examiner notes that the specification states that Applicant believes that the rice-actin promoter in varieties 'F1117' and 'GA21' more efficiently drives expression of the mutant EPSPS gene in pollen than do the maize histone promoter and CaMV35s-*Arabidopsis* histone promoter of 'GG25' and 'GJ11', respectively. Applicant also states that selection of a promoter which is poorly expressed in pollen, one may intentionally engineer herbicide resistant plants in which male-sterility can be induced through application of herbicides (page 79 of the specification). But the Examiner notes that ~~not~~ limitation is recited in the claims as to what promoter is operably linked to the first EPSPS transgene of the first parent that is capable of being rendered male-sterile by treatment with glyphosate, and that Applicant does not adequately describe the genus of promoters that could be used to make such a first parent maize plant. In addition, the Examiner notes that the instant specification does not describe what features of a promoter that is operably linked to an EPSPS transgene has, that leads to poor expression of said transgene in pollen, other than the CaMV35S, maize histone and *Arabidopsis* histone promoters (see paragraph spanning pages 78-79 of the specification).

Applicant argues that the breeding steps, set forth in claim 83, are fully described, and that specific examples of breeding protocols within the scope of the claims are also described. Applicant also argues that method for the production of hybrid corn seed using inducible male-sterility, types of inbred parent lines are also described (page 7, 2nd paragraph of the response). These arguments are addressed above as directed to the starting materials required to practice the claimed method.

Applicant's arguments as directed to breeding methods in the paragraph spanning pages 7-8 of the response are not deemed relevant to the instant rejection, which is directed to the adequate written description of the starting materials of the claimed method.

9. Claims 83-87 and 96-99 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of plant breeding comprising a first female parent maize plant comprising a first EPSPS transgene operably linked to a CaMV35S, maize histone or *Arabidopsis* histone promoter, wherein said first female parent maize plant is capable of being rendered male-sterile by treatment of said maize plant with glyphosate, does not reasonably provide enablement for a method of plant breeding using any other maize plants comprising an EPSPS transgene operably linked to other promoters that are capable of being rendered male-sterile by treatment with glyphosate. This rejection has been modified from the rejection of record as set forth in the last Office action mailed 3 October 2002. Applicant's arguments filed 4 February 2003 have been fully considered but they are not persuasive.

The Feng Declaration, outlined on pages 8-10 of the response, has been addressed above.

Applicant argues that while not every EPSPS event exhibits inducible male sterility, all that is relevant is that such plant can be prepared without undue experimentation (page 10, 2nd paragraph of the response). This argument is not found to be persuasive because what is relevant is that one of skill in the art must be able to

make and use the invention within the full scope of the claims. In the instant case, Applicant has failed to adequately teach one of skill in the art how to make and use all maize plants comprising a first EPSPS transgene wherein said plant is capable of being rendered male-sterile by treatment of said plant with glyphosate.

Applicant argues the 'GG25' and 'GJ11' are transformation events and not maize lines and that these events may be transferred by plant breeding techniques into essentially any other maize plant (page 10, 3rd paragraph, and the paragraph spanning pages 10-11 of the response). This argument is not found to be persuasive because the instant claims are not limited to maize plants comprising a first EPSPS transgene that is capable of being rendered male-sterile by treatment of said plant with glyphosate that are produced from 'GG25' or 'GJ11'.

Applicant argues that the legal standard for enablement does not require that Applicants demonstrate enablement for all possible claimed iterations but must bear only a reasonable relationship to the scope of the claims, citing *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) (page 11, 2nd paragraph of the response). The Examiner responds that *In re Fisher* also teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical

reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.". In the instant case, the unpredictability is directed to the first parent maize plant and/or the DNA construct used to make said first parent maize plant comprising a first EPSPS transgene that is capable of being rendered male-sterile by treatment of said plant with glyphosate.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Amy Nelson".

David H. Kruse, Ph.D.
9 April 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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